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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,155	10/14/2004	Oliver Schadt	MERCK-2932	9151

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EXAMINER

GRAZIER, NYEEMAH

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/511,155	Applicant(s) SCHADT ET AL.	
	Examiner Nyeemah Grazier	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. ACTION SUMMARY

Claims 1-19 are currently pending in the instant application.

II. PRIORITY

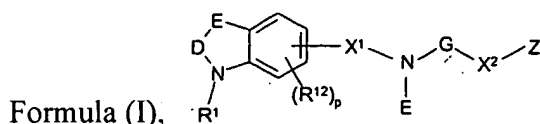
This application is a 371 of PCT/EP03/03806, filed on April 11, 2003. Applicant's claim for priority under 35 U.S.C. § 119(a-d) to foreign application Germany 10217006.1 filed on April 16, 2002 is hereby acknowledged. However, the applicant has not filed a certified copy of the original France 02 05863 application and an English translation as required by 35 U.S.C. § 119(b).

III. RESTRICTION-LACK OF UNITY OF INVENTION

Restriction is required under 35 U.S.C. 121 and 372 because the instant application contains the following inventions or groups of inventions which are not so linked to form a single general inventive concept under PCT Rule 13.1. Therefore a restriction is required according to the provision of PCT Rule 13.2.

The instant application contains Markush practice. However, pursuant to Section B (Markush Practice) MPEP § 1850 (B), the invention does not meet the unity of invention criteria because (1) the core structure is not the unifying criteria and (2) the variables do not belong to a "recognized class of chemical compounds in the art to which the invention pertains." MPEP § 1850 (B) (2004).

Art Unit: 1626



, as recited in Claim 1 is the genus. The special

technical feature is the unsaturated or saturated indole ring. Unity of invention is lacking

because the core is not novel, *infra*. Claims 1-19 are drawn to more than one inventive concept

(as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,...

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely-divergent variables in the compound of Formula (I), such as **D, E, X1, R1, E, G, X2, Z**, etc. a precise listing of inventive groups cannot be made. *The following groups are exemplary:*

Group I: Claims 1-16, drawn to compounds and compositions, method of making and the method of using the compounds and compositions of formula (I), wherein:

D-E is $R_2C=CR_4$;

X1 is $(CHR_7)_g$;

E is H; A, $(CH_2)_nHet$, $(CH_2)_nAr$ or cycloalkyl having 3 to 7 carbon atoms;

G is an optionally substituted alkylene radical having 1 to 4 carbon atoms, where the substituents are selected from the meanings indicated for R_4 ;

X2 is a bond or $(CHR_7)_g$;

Z is 2,3-dihydro-1,4-benzoxin-6-yl;

Group II: Claims 1-16 drawn to compounds, compositions, method of making and the method of using the compounds and compositions of formula (I) wherein:

D-E is $R_2C=CR_4$;

X1 is $(CHR_7)_g$;

E/G E and G together with the nitrogen atom to which they are bonded, form a piperidine ring;

Art Unit: 1626

X2 is a bond or (CHR₇)_g;

Z is 2,3-dihydro-1,4-benzoioxin-6-yl;

Group III: Claims 1-16 drawn to compounds, compositions, method of making and the method of using the compounds and compositions of formula (I) wherein:

D-E is R₂C=CR₄;

X1 is (CHR₇)_g;

E/G E and G together with the nitrogen atom to which they are bonded, form a piperazine ring;

X2 is a bond or (CHR₇)_g;

Z is 2,3-dihydro-1,4-benzoioxin-6-yl;

Group IV: Claims 1-16 drawn to compounds, compositions, method of making and the method of using the compounds and compositions of formula (I) wherein:

D-E is R₂C=CR₄;

X1 is (CHR₇)_g;

E/G E and G together with the nitrogen atom to which they are bonded, form a piperazine ring;

X2 is a bond or (CHR₇)_g;

Z is 1,3 pyrimidine ring;

Art Unit: 1626

Group V: Claims 1-16 drawn to compounds, compositions, method of making and the method of using the compounds and compositions of formula (I) wherein:

D-E is $R_2C=CR_4$;

X1 is $(CHR_7)_g$;

E/G E and G together with the nitrogen atom to which they are bonded, form a piperidine ring;

X2 is a bond or $(CHR_7)_g$;

Z is pyrazole;

Group VI: Claims 1-16 drawn to compounds, compositions, method of making and the method of using the compounds and compositions of formula (I) wherein:

D-E is $R_2C=CR_4$;

X1 is $(CHR_7)_g$;

E/G E and G together with the nitrogen atom to which they are bonded, form a piperazine ring;

X2 is a bond or $(CHR_7)_g$;

Z is phenyl;

Group VII: Claims 1-16 drawn to compounds, compositions, method of making and the method of using the compounds and compositions of formula (I) wherein:

D-E is $R_2C=CR_4$;

X1 is $(CHR_7)_g$;

Art Unit: 1626

E/G E and G together with the nitrogen atom to which they are bonded, form a piperazine ring;

X2 is a bond or (CHR7)g;

Z is quinolinyl;

Group VIII: Claims 1-16 drawn to compounds, compositions, method of making and the method of using the compounds and compositions of formula (I) wherein:

D-E is $R_2C=CR_4$;

X1 is (CHR7)g;

E/G E and G together with the nitrogen atom to which they are bonded, form a piperazine ring;

X2 is a bond or (CHR7)g;

Z benzofuran;

Group IX: Claim 18 drawn to the compound of formula II.

Group X: Claim 19 drawn to the compound of formula III.

The abovementioned groups are exemplary and therefore the list of groups as described is **not exhaustive**. Applicant is encouraged to particularly describe a compound that is not listed above by specifically pointing out the definitions of each variable.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. As stated above, this is not an

exhaustive list, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter claimed in this application.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) the instant invention lacks unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-X** is an indole ring and is therefore the *technical feature*. However, this technical feature is not a *special technical feature*, because it fails to define a contribution over the prior art (*See Macor, et al.*, US 6,255,306, for example). Therefore, Claims 1-19 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, or a method of use.

Furthermore, with respect to **Groups I-X**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to

Art Unit: 1626

different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention and a single compound, including an exact definition of all substituents and variables wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl and each subsequent variable position.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

Telephonic Inquiry

A telephone call was made to Anthony Zelano, Esquire on or about January 13, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

IV. CONCLUSION

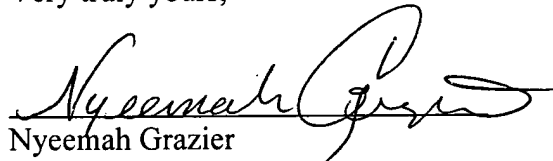
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

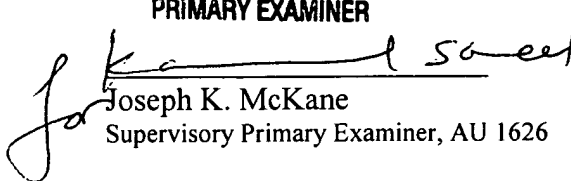
Art Unit: 1626

Very truly yours,


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